

Amendments to the Specification

Please replace the paragraph at page 50, beginning at line 2, under the heading DEPOSITS with the following:

Applicant(s) have made a deposit of at least 2500 seeds of hybrid maize plant 34N16 and inbred parent plants GE568102 and GE534776 with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, VA 20110-2209 USA, ATCC Deposit Nos. _____, and _____, respectively. The seeds deposited with the ATCC on _____, and _____, respectively were taken from the deposit ~~A deposit of the seed of hybrid 34N16 is and has been maintained by Pioneer Hi-Bred International, Inc., 800 Capital Square, 400 Locust Street, Des Moines, Iowa 50309-2340, since prior to the filing date of this application. Access to this deposit will be available during the pendency of the application to the Commissioner of Patents and Trademarks and persons determined by the Commissioner to be entitled thereto upon request. Upon allowance of any claims in the application, the Applicant(s) will make available to the public, pursuant to 37 C.F.R. § 1.808, without restriction a sample(s) of the deposit of at least 2500 seeds of hybrid maize plant 34N16 and inbred parent plants GE568102 and GE534776 with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209. This deposit of seed of hybrid maize plant 34N16 and inbred parent plants GE568102 and GE534776 will be maintained in the ATCC Depository, which is a public depository, for a period of 30 years, or 5 years after the most recent request, or for the enforceable life of the patent, whichever is longer, and will be replaced if it becomes nonviable during that period. The seeds deposited with the ATCC will be taken from the same deposit maintained at Pioneer Hi-Bred and described above.~~ Additionally, Applicant(s) ~~will meet have satisfied~~ all the requirements of 37 C.F.R. §§ 1.801 - 1.809, including providing an indication of the viability of the sample ~~when the deposit is made upon deposit~~. This deposit of Hybrid Maize Line 34N16 will be maintained without restriction in the ATCC Depository, which is a public depository, for a period of 30 years, or 5 years after the most recent request, or for the enforceable life of the patent, whichever is longer, and will be replaced if it ever becomes nonviable during that period. Applicant(s) have no authority to waive any restrictions imposed by law on the transfer of biological material or its transportation in commerce. Applicant(s) do not waive any infringement of their rights granted under this patent or under the Plant Variety Protection Act (7 USC 2321 et seq.).

Amendments to the Claims

Claim 1 (Original): Hybrid maize seed designated 34N16, representative seed of said hybrid 34N16 having been deposited under ATCC accession number _____.

Claim 2 (Original): A maize plant, or its parts, produced by the seed of claim 1.

Claim 3 (Original): Pollen of the plant of claim 2.

Claim 4 (Original): An ovule of the plant of claim 2.

Claim 5 (Currently amended): A tissue culture of regenerable cells or protoplasts of said cells of a hybrid maize plant 34N16, representative seed of said hybrid maize plant 34N16 having been deposited under ATCC accession number _____, wherein the tissue culture regenerates plants capable of expressing all the morphological and physiological characteristics of said hybrid maize plant 34N16.

Claim 6 (Previously amended): The tissue culture according to claim 5, the cells or protoplasts of said cells having been isolated from a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.

Claim 7 (Original): A maize plant, or its parts, regenerated from the tissue culture of claim 5 and capable of expressing all the morphological and physiological characteristics of hybrid maize plant 34N16, representative seed having been deposited under ATCC accession number _____.

Claim 8 (Currently amended): The maize plant of claim 2 wherein said maize plant further comprises a genetic factor conferring an introgressed cytoplasmic gene that confers male sterility.

Claims 9-11 (Canceled)

Claim 12 (Currently amended): A maize plant according to claim 2, wherein the genetic material of said plant further comprises one or more mutant genes or transgenes which have been introgressed therein, said mutant genes or transgenes selected from the group consisting of: a plant disease resistance gene, an insect resistance gene, a herbicide resistance gene, and a male sterility gene.

Claims 13-19 (Canceled)

Claim 20 (Original): A maize plant, or its parts, having all the morphological and physiological characteristics of the plant of claim 2.

Claim 21 (Currently amended): The maize plant of claim 20 wherein said maize plant further comprises a genetic factor conferring an introgressed cytoplasmic gene that confers male sterility.

Claims 22-24 (Canceled)

Claim 25 (Currently amended): A maize plant according to claim 20, wherein the genetic material of said plant further comprises one or more mutant genes or transgenes which have been introgressed therein, said mutant genes or transgenes selected from the group consisting of: a plant disease resistance gene, an insect resistance gene, a herbicide resistance gene, and a male sterility gene.

Claims 26-32 (Canceled)

Claim 33 (Currently amended): A method of making a hybrid maize plant designated 34N16 comprising:
crossing an inbred maize plant GE568102, deposited as _____ with a second inbred maize plant GE534776, deposited as _____; and
developing from the cross a said hybrid maize plant representative seed of which having been deposited under ATCC Accession Number _____.

Claims 34-40 (Canceled)

Claim 41 (Currently amended): A method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 with a ~~genetic factor~~ transgene conferring male sterility.

Claim 42 (Currently amended): ~~The method of claim 41 wherein a~~ A male sterile maize plant is produced by the method of claim 41.

Claim 43 (New): A method of making an F1 hybrid maize plant comprising:
1) introgressing a mutant gene or a transgene that encodes a product that confers insect resistance into at least one of inbred maize parent plants GE568102 and GE534776, representative samples of which have been deposited as _____ and _____ respectively, and
2) crossing said inbred maize parent plants to produce said F1 hybrid maize plant.

Claim 44 (New): The maize plant produced by the method of claim 43 wherein said mutant gene or transgene is an insect resistance gene encoding a *Bacillus thuringiensis* polypeptide.

Claim 45 (New): The maize plant produced by the method of claim 43.

Claim 46 (New): A method of making an F1 hybrid maize plant comprising:
1) introgressing a mutant gene or a transgene that encodes a product that confers herbicide resistance into at least one of inbred maize parent plants GE568102 and GE534776, representative samples of which have been deposited as _____ and _____ respectively, and
2) crossing said inbred maize parent plants to produce said F1 hybrid maize plant.

Claim 47 (New): The maize plant produced by the method of claim 46 wherein said mutant gene or transgene is an herbicide resistance transgene selected from the group consisting of: a transgene conferring glyphosate resistance, a transgene conferring glufosinate resistance, a mutant gene or transgene conferring imidazolinone resistance and a mutant gene or transgene conferring sulfonylurea resistance.

Claim 48 (New): The maize plant produced by the method of claim 46.

Claim 49 (New): A method of making an F1 hybrid maize plant comprising:

- 1) introgressing a mutant gene or a transgene that encodes a product that confers disease resistance into at least one of inbred maize parent plants GE568102 and GE534776, representative samples of which have been deposited as _____ and _____ respectively, and
- 2) crossing said inbred maize parent plants to produce said F1 hybrid maize plant.

Claim 50 (New): The maize plant produced by the method of claim 49.

Claim 51 (New): A method of making an F1 hybrid maize plant comprising:

- 1) introgressing a gene that confers male sterility into at least one of inbred maize parent plants GE568102 and GE534776, representative samples of which have been deposited as _____ and _____ respectively, and
- 2) crossing said inbred maize parent plants to produce said F1 hybrid maize plant.

Claim 52 (New): The method of claim 51 wherein said F1 hybrid maize plant further comprises said gene that confers cytoplasmic male sterility.

Claim 53 (New): The maize plant produced by the method of claim 51.

Claim 54 (New): A method of making an F1 hybrid maize plant comprising:

- 1) introgressing a gene that encodes a product that confers imidazolinone resistance into at least one of inbred maize parent plants GE568102 and GE534776, representative samples of which have been deposited as _____ and _____ respectively, and
- 2) crossing said inbred maize parent plants to produce said F1 hybrid maize plant.

Claim 55 (New): The maize plant produced by the method of claim 54.

Claim 56 (New): A method of making an F1 hybrid maize plant comprising:

1) introgressing a mutant gene or a transgene that encodes a product that modifies fatty acid metabolism, that decreases phytate content, or that modifies starch metabolism into at least one of inbred maize parent plants GE568102 and GE534776, representative samples of which have been deposited as _____ and _____ respectively, and

2) crossing said inbred maize parent plants to produce said F1 hybrid maize plant.

Claim 57 (New): The maize plant produced by the method of claim 55.

Claim 58 (New): The maize plant produced by the method of claim 43 wherein said maize plant exhibits no statistically significant variation from 34N16, other than variation caused by the addition of said mutant gene or transgene, and wherein significance is determined at a 5% significance level when grown in the same environmental conditions as 34N16.

REMARKS

The present application relates to hybrid maize plant and seed 34N16. Claims 9-11, 13-19, 22-24, 26-32, 34-40 have been canceled. Claims 43-58 have been added. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

Detailed Action

A. Status of the Application

Applicant acknowledges the indefiniteness rejection and the art rejection of record of claims 10, 14, 18, 23, 27 and 31 have been overcome.

B. Specification

Applicant submits the Deposit section on page 50 has been amended in order to properly include both the hybrid maize plant 34N16 and the inbred parent plants GE568102 and GE534776 within the Deposit paragraph. The changes do not add new matter as there is literal support for the minor changes on pages 7 in the originally filed specification. The specification has now been amended to correct these minor changes.

In addition, Applicant respectfully submits that the actual ATCC deposit of the two inbred plants will be delayed until the receipt of notice that the application is otherwise in condition for allowance, in compliance under 37 C.F.R. §§ 1.801-1.809. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination and the name and address of the depository. The claims will also be amended to recite the ATCC deposit number. Applicant submits that at least 2,500 seeds of hybrid maize plant 34N16 and the inbred parents GE568102 and GE534776 will be deposited with the ATCC. Applicant further asserts that the deposits will be made without restriction

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 8, 11-19, 21, 24-32, 39, and 42 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point and distinctly claim the subject

matter which Applicant regards as the invention, as stated in the last Office Action for claims 5-8, 10-19, 21, and 23-32.

Applicant respectfully traverses this rejection. Applicant wishes to reiterate that it is well known in the art that the hybrid 34N16 will represent elite germplasm produced from the crossing of inbred parent lines GE568102 and GE534776 for character traits of major importance which will subsequently be used in a breeding population to further those elite traits. Applicant further asserts that it would be understood by one skilled in the art that the claimed maize plant or its parts contain at least 50% of the alleles inherited from the hybrid maize plant 34N16 having been deposited under ATCC Accession No. to be disclosed upon allowance of subject matter. Applicant further asserts, "[W]hen not defined by Applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art", thereby alleviating this rejection. See *In re Sneed*, 710 F.2d 1544, 218 U.S.P.Q. 385 (Fed. Cir. 1983); *See also* MPEP § 2111.02. However, in order to expedite prosecution Applicant has canceled claims 9-11, 13-19, 22-24, 26-32, and 34-40, thereby alleviating this rejection to said claims.

The Examiner rejects claim 39 as indefinite for the recitation "34N16 maize plant ... deriving at least 50% of its alleles from 34N16" as confusing.

Applicant has now canceled claim 39, thus alleviating this rejection.

Claim 42 stands rejected as indefinite for failing to further limit claim 41.

Applicant has now amended claim 42 to read --A male sterile maize plant produced by the method of claim 41--, as suggested by the Examiner. Applicant thanks the Examiner for the suggested language.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 11, 15, 19, 24, 28, 32, 34 and 38-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that there is

no literal basis in the specification for the 50% allelic derivation language. Further the Examiner states that there is no basis for the double haploid method.

Applicant respectfully traverse this rejection. However, in an effort to expedite prosecution, Applicant has canceled claims 11, 15, 19, 24, 28, 32, 34 and 38-40 and added new claims 43-54, alleviating this rejection. In addition, Applicant has now amended claims 12 and 25 to include --contains one or more mutant genes or transgenes which have been introgressed therein, said mutant genes or transgenes selected from the group consisting of: a plant disease resistance gene, an insect resistance gene, a herbicide resistance gene, and a male sterility gene--, thereby limiting the claims to the types of transgenes that may be introduced and that are supported by the specification on pages 42-48, as suggested by the Examiner. Applicant therefore respectfully requests withdrawal of the above rejections.

Claim 33 stands rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is more nearly connected, to make and/or use the invention. The Examiner states the claim is drawn towards a method of making a hybrid plant designated 34N16 comprising crossing inbred maize plants GE568102 and GE534776, however the Examiner states the terms of this deposit are not known.

Applicant respectfully traverses this rejection. Applicant herein submits the Deposits section has been amended in order to properly include both the hybrid maize plant 34N16 and the inbred parents GE568102 and GE534776 within the Deposit paragraph on page 50. The changes do not add new matter as there is literal support for the minor changes on page 7 in the originally filed specification. The specification has now been amended to correct these minor changes. Applicant thanks the Examiner for pointing out this inadvertent mistake.

In addition Applicant submits that the actual ATCC deposit will be delayed until receipt of notice that the application is otherwise in condition for allowance. As provided in 37 C.F.R. §§ 1.801-1.809, Applicant wishes to reiterate they will refrain from deposit of hybrid 34N16 and inbred parents GE568102 and GE534776 until allowable subject matter is indicated. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, description of the deposited biological materials sufficient to specifically identify and to permit examination and the name

and address of the depository. The claims will also be amended to recite the proper ATCC deposit numbers. The Applicant provides assurance that:

- a) during the pendency of this application access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c) the deposit will be maintained in a public depository for a period of thirty years, or five years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit will be conducted (see 37 C.F.R. § 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Therefore, Applicant submits at least 2500 seeds of hybrid maize plant 34N16 and the inbred parents GE568102 and GE534776 will be deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02) Such action is respectfully requested.

Claims 8-19, 21-32 and 34-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office Action for claims 8-19 and 21-32. The Examiner stated that claims 12, 15, 25, 28 and dependents thereon are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plant. The Examiner further stated that claims 8, 16, 19, 21, 29, 32 and dependents thereon are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants.

Applicant respectfully traverses this rejection. . The Examiner states the "the introgression of a gene of interest would in fact result in the introduction of additional, uncharacterized genetic material." Applicant asserts that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested

material. As stated in Poehlman *et al.* (1995) on page 334, submitted in the Information Disclosure Statement, a backcross derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." Applicant further points out that cytoplasmic male sterility genes do not introduce linked nuclear genes. Wych (1988) on page 585-586, submitted in the Information Disclosure Statement, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile inbred to be the same variety as the F1 hybrid produced with the fertile version of the inbred. Applicant also refers the Examiner to Openshaw *et al.* submitted herewith, which states the "the backcross breeding procedure is being used widely to transfer simply inherited traits into elite genotypes...Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm."

Nonetheless, in an effort to expedite prosecution, Applicant has canceled claims 9-11, 13-19, 22-24, 26-32, and 34-40 and amended claims 12 and 25 to include --contains one or more mutant genes or transgenes which have been introgressed therein, said mutant genes or transgenes selected from the group consisting of: a plant disease resistance gene, an insect resistance gene, a herbicide resistance gene, and a male sterility gene--, thereby limiting the claims to the types of transgenes that may be introduced and that are supported by the specification as aforementioned. Applicant respectfully submits the claims come within the purview of the written description requirement and request reconsideration.

Claims 8, 12-19, 21, 25-32 and 34-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons stated in the last Office Action for 8, 12-19, 21 and 25-32.

Applicant respectfully traverses this rejection. Applicant herein submits the Deposit section has been amended in order to properly include both hybrid maize plant 34N16 and the inbred parents GE568102 and GE534776 within the Deposit paragraph on page 50. The changes do not add new matter as there is literal support for the minor changes on page 7 in the originally

filed specification. The Specification has now been amended to correct these minor changes. The Applicant further provides assurance that at least 2500 seeds of hybrid maize plant 34N16 and the inbred parents GE568102 and GE534776 have been deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02).

The Examiner states in the Advisory Action of June 11, 2003, that the deposit "is not sufficient to enable or describe the exemplified hybrid, but is not sufficient to enable or describe derivatives thereof which somehow simultaneously contain an additional gene while maintaining all of its desirable characteristics, and which do not contain unwanted genes linked to the introgressed gene of interest, which unwanted genes would interfere with the collection of traits that made the hybrid patentable in the first place." Transformation and backcrossing are two techniques that may be utilized to add a desirable trait to an already developed inbred or hybrid. As described herein and in the specification, such techniques are well known to those of ordinary skill in the art and may be practiced on the deposited material. Applicants have also added claim 58 to further describe the line produced in such a manner by traits that do not vary from the deposited line at a 5% significance level when measured in the same environmental conditions. Phenotypic traits, an identifying characteristic, are a method utilized by those of ordinary skill in the art to compare two lines, and are the method used by the patent office to evaluate the novelty of the deposited line itself."

In addition, Applicant submits a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601. One of ordinary skill in the art of plant breeding would know how to evaluate the traits of two plant varieties to determine if there is no statistically significant variation when determined, for example, at a 5% significance level and when grown in the same environmental conditions between the traits expressed by those varieties. Applicant claims progeny produced by backcrossing with 34N16 and retaining phenotypic characteristics of 34N16. Distinguishing identifying characteristics in the chemical and biotechnological arts, dealing with DNA, are those such as: partial structure, physical and/chemical properties, functional characteristics, known or disclosed correlation between structure and function, method of making, and combinations of the above. In plants, phenotypic characteristics are identifying characteristic correlated with DNA structure. In addition, in an

effort to expedite prosecution claims 9-11, 13-19, 22-24, 26-32, and 34-40 have been canceled. For the reason aforementioned, it is respectfully submitted that Applicants' claims are sufficiently enabled by the specification.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 8-19 and 21-40 under 35 U.S.C. § 112, first paragraph.

Summary

Applicant acknowledges that claims 1-7, 20, and 41 are allowed.

Applicant acknowledges that claims 1-10, 12-14, 16-18, 20-23, 25-27 and 29-31 are deemed free of the prior art. The Examiner further states the prior art fails to teach or fairly suggest plants which derive 50% or more of their alleles from the exemplified hybrid. This clearly indicates that hybrid maize plant 34N16 as a whole is considered to be distinguishable from the prior art for the purposes of novelty and non-obviousness. Therefore, Applicant respectfully submits that the deposit of the representative seed of 34N16 and inbred parents GE568102 and GE534776 should satisfy the description requirement. In light of the above, Applicant respectfully submits that the rejections under 35 U.S.C. § 112, first paragraph as improper and requests reconsideration and withdrawal of these rejections.

Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested.

This is a request under the provision of 37 C.F.R. § 1.136(a) to extend the period for filing a response in the above-identified application for one month from June 11, 2003 to July 11, 2003. Applicant is a large entity; therefore, a check is enclosed in the amount of \$110.00 for one month to cover the cost of the extension.

Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



LILA A.T. AKRAD, Reg. No. 52,550
McKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No. (515) 288-3667
Fax No. (515) 288-1338
CUSTOMER NO: 27142

Attorneys of Record

- pw/LA -